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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,374	10/11/2005	Daisuke Yasokawa	264042US0PCT	8913
22850	7590	08/21/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BADR, HAMID R	
			ART UNIT 1794	PAPER NUMBER
			NOTIFICATION DATE 08/21/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/518,374	Applicant(s) YASOKAWA ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/28/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The information disclosure statement filed 3/28/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Thus, Yasogawa referred to therein has not been considered.

Claim objections

Claim 1 is objected to for "An milk-coagulating". The indefinite article "An" has been inappropriately used. Correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the

Art Unit: 1794

requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 3 is indefinite given that it is not clear if the pure enzyme was assayed to have a "stable" pH and temperature range or the impure enzyme as precipitated with ammonium sulfate was assayed in the presence of ammonium sulfate. On the other hand the word "stable" makes the claim indefinite. For enzyme characterization, the pure enzyme is assayed to determine the optimum pH and temperature of activity and the pH and temperature are usually reported as [optimum pH] and [optimum temperature]. It is unclear what is meant by "stable pH range" and "stable temperature range". It is not clear what the applicant regards as the invention.

Art Unit: 1794

5. Claim 4 is indefinite for "Paenibacillus sp". It is unclear what is meant by "Paenibacillus sp." Since there are a few Paenibacillus sp. with extracellular proteolytic activities, it is not clear what the applicant regards as the invention.

6. Claim 6 is indefinite for "a cheese-like food". It is not clear what is meant by "cheese-like". It is unclear what the applicant regards as the invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dancer et al. (1996, The proteases of American foulbrood scales; hereinafter R1).

9. R1 discloses proteolytic activity of Paenibacillus larvae. R1 discloses that the pH optimum for the proteolytic activity of this organism is optimal at about pH 6.8 (page 82, col. 1, lines 1-2).

10. R1 discloses that the protease of the mentioned organism requires calcium ions for general stability (page 82, col. 2, lines 4-8).

11. R1 discloses that the protease of the mentioned organism has an optimal temperature range of 60-65C. A "stable" temperature range of 40-50C is presently claimed for the protease and not an [optimum] temperature range as disclosed by R1.

Art Unit: 1794

However, the enzyme disclosed by R1 with an optimum temperature of 60-65C will be inherently stable at 40-50C as presently claimed.

12. R1 discloses a molecular mass of 21-23 kDa as determined by SDS-PAGE method. A molecular mass of 35-37 kDa is presently claimed for the presently claimed protease. R1 explains that the samples were taken from degraded cadavers (page 83, col. 2, SDS_PAGE lines 7-8). Given that R1 discloses that the molecular weight of the enzyme is measured from samples taken from degraded cadavers and is thus an apparent molecular mass, it is clear that if such samples were taken from the organism directly, the molecular weight would overlap that presently claimed.

13. R1 discloses that the protease of *P. larvae* is a strong protease that can coagulate milk (Page 85, col. 2, Discussion; lines 1-3).

14. Given that the protease of *P. larvae* coagulates milk, the k-casein is being hydrolyzed. The cleaving of the peptide bond between Thr94-Met95 will be inherent in the activity of this enzyme.

15. The precipitation of globular proteins using various saturations of ammonium sulfate is an old and very well known and established technique in the art. The technique is known as salting out. The saturation range of 50-80% as presently claimed can be obviously determined by one of ordinary skill in the art.

16. R1 is silent regarding the application of the protease of *P. larvae* for cheese making. However, given that R1 discloses the milk coagulating activity of the protease disclosed and given that cheese making process using a protease is an old and well

Art Unit: 1794

established art and animal proteases and microbial ones are known in the art, it would be obvious to one of skill in the art to use such protease in cheese making process.

17. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R1 and characterize a milk coagulating enzyme from a *Paenibacillus* sp. One would do so to benefit from a new source of protease which may be used in the food industry. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success to isolate and characterize such a protease from *Paenibacillus* sp.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794